Patent Application
Attorney's Docket No. 016800-429

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	)	
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Olivier DE LACHARRIERE et al	)	Group Art Unit:
	)	
Application No.:	)	Examiner:
	)	
Filed: December 14, 2000	)	
	)	
For: USE OF A SUBSTANCE P ANTAGONIST(S) IN COSMETIC COMPOSITIONS FOR TREATMENT OF SENSITIVE SKIN	)	Continuation of Appln. No. 08/611,549, filed March 11, 1996, now allowed

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination on the merits, kindly amend the above-identified application as follows:

IN THE CLAIMS:

Please cancel Claim 1, without prejudice or disclaimer.

Kindly add the following new Claims 25-114:

--25. A cosmetic or dermatological method for treating or preventing sensitive skin of an individual in need of such treatment, comprising topically applying to said sensitive skin an effective amount of at least one substance P antagonist-containing composition, and wherein said effective amount of said at least one substance P antagonist

is formulated into a topically applicable cosmetically- or dermatologically-acceptable medium therefor.

--26. The method of Claim 25, wherein said substance P antagonist is a compound that (i) reduces the extravasation of plasma through the vascular wall caused by capsaicin or by antidromic nerve excitation, or (ii) inhibits the contraction of the smooth muscles induced by the administration of substance P, or (iii) a combination thereof, and wherein said effective amount of said at least one substance P antagonist is formulated into a topically applicable cosmetically-acceptable medium therefor.

--27. The method of Claim 25, wherein the method of treatment or prevention of sensitive skin alleviates or prevents at least one neurogenic manifestation selected from the group consisting of skin irritation, desquamation, erythema, side effects of dysesthesia, side effects of overheating, and skin pruritus.

--28. The method of Claim 25, wherein the substance P antagonist is a nitrogen-containing heterocyclic compound.

--29. The method of Claim 25, wherein said substance P antagonist is a peptide.

--30. The method of Claim 25, wherein said substance P antagonist is a peptide selected from the group consisting of sendide and spantide II.

--31. The method of Claim 25, wherein said substance P antagonist is selected from the group consisting of 2-tricyclyl-2-aminoethane, spirolactame, quinuclidine, azacyclic, aminopyrrolidine, piperidine, aminoazeheterocyclic and isoindole compounds.

--32. The method of Claim 25, wherein the substance P antagonist is contained in an amount ranging from between 0.000001 to 5 percent by weight of the total weight of the composition.

--33. The method of Claim 32, wherein the substance P antagonist is contained in an amount ranging from between 0.0001 to 0.1 percent by weight of the total weight of the composition.

--34. The method of Claim 25, wherein said substance P antagonist is administered in a topically administrable form selected from the group consisting of aqueous and hydroalcoholic solutions, water-in-oil and oil-in-water emulsions, microemulsions, aqueous gels, anhydrous gels, serums and vesicular dispersions.

--35. The method of Claim 25, wherein said substance P antagonist is co-administered with at least one agent selected from the group consisting of anti-bacterials, anti-parasiticals, anti-fungals, anti-inflammatories, anti-pruriginous agents, anesthetics, anti-virals, keratolytic agents, anti-free radical agents, anti-seborrheal agents, dandruff-

fighting agents, acne-fighting agents, skin differentiating modulating agents, skin proliferation modulating agents, and skin pigmentation modulating agents.

--36. The method of Claim 25, wherein said substance P antagonist is co-administered with at least one agent selected from the group consisting of lidocaine, chlorohydrate, non-steroidal anti-parasiticals, and anti-inflammatory agents.

--37. The method of Claim 25, wherein said substance P antagonist is contained in a cosmetic or dermatological composition selected from the group consisting of cleansing creams, make-up removal creams, foundation creams, sunscreen creams, liquid foundations, make-up removal lotions, skin-care lotions, sunscreen lotions, skin-care gels, skin-care foams, tanning lotions, bath preparations, after-shave gels, after-shave lotions, depilatory creams, insect sting compositions, soaps, cleansing bars, aerosol compositions, hair care compositions, and mouth care compositions.

--38. The method of Claim 37, wherein said hair care composition is selected from the group consisting of a shampoo, setting lotion, hair treatment lotion, hair cream or gel, hair colorant, restructuring lotion, permanent wave composition, and an anti-hair loss lotion or gel.

--39. The method of Claim 37, wherein said mouth care composition is a toothpaste.

--40. The method of Claim 25, wherein said substance P antagonist is contained in an emulsion.

--41. The method of Claim 37, wherein said mouth care composition contains an ingredient selected from the group consisting of a surfactant, thickener, wetting agent, polishing agent, fluoride, and a sweetener.

--42. The method of Claim 40, wherein the emulsion contains a fatty phase, which comprises 5% to 80% by weight of the substance P antagonist-containing emulsion.

--43. The method of Claim 40, wherein the emulsion contains an oil, an emulsifier, and a co-emulsifier.

--44. The method of Claim 43, wherein the amount of emulsifier and co-emulsifier ranges from 0.3 to 30% by weight.

--45. The method of Claim 25, wherein said substance P antagonist is administered together with at least one additive selected from the group consisting of a water-absorbent or lipophilic gelling agent, water-absorbent or lipophilic active ingredient, preservative, antioxidant, solvent, perfume, filler, screen and coloring substance.

--46. The method of Claim 25, wherein said substance P antagonist is administered together with at least one oil selected from the group consisting of a mineral oil, vegetable oil, animal oil, synthetic oil, silicone-containing oil, and a fluorinated oil.

--47. The method of Claim 25, wherein said substance P antagonist is administered with at least one active ingredient selected from the group consisting of protein and protein hydrolyzates, amino acids, polyalcohols, urea, allantoin sugars and sugar derivatives, vitamins, hydroxy acids, retinol, tocopherol, ceramides, essential oils, and salicylic acid.

--48. The method of Claim 26, wherein said substance P antagonist is administered together with at least one agent selected from the group consisting of an agent that affects at least one of skin differentiation, proliferation and pigmentation, vitamin D, an estrogen, antibacterial agent, antiparasitic agent, antifungal agent, anti-inflammatory agent, anesthetic agent, anti-pruriginous agent, antiviral agent, keratolytic agent, anti-free radical agent, anti-seborrhea agent, anti-dandruff agent, and anti-acne agent.

--49. The method of Claim 25, wherein said substance P antagonist is administered together with at least one active ingredient that elicits an irritant side effect.

--50. The method of Claim 49, wherein said active ingredient is selected from the group consisting of an α-hydroxy acid, β-hydroxy acid, α-ketonic acid, β-ketonic acid,

retinoid, anthraline, anthranoid, peroxide, minoxidil, lithium salt, antimetabolite, and vitamin D compound.

--51. The method of Claim 25, wherein said substance P antagonist is contained in a cosmetically-acceptable medium.

--52. The method of Claim 25, which comprises topical application of said substance P antagonist to at least one of the skin, hair, or mucous membranes.

--53. The method of Claim 25, wherein said sensitive skin is skin that is characterized by at least one symptom selected from the group consisting of tingling, burning, itching, and erythema after topical application of capsaicin.

--54. The method of Claim 53, wherein said at least one symptom is observed between 3 and 20 minutes after capsaicin application.

--55. A cosmetic or dermatological method for treating or preventing sensitive, but not allergic, skin of an individual in need of such treatment, comprising topically applying to said sensitive skin an effective amount of at least one substance P antagonist-containing composition, and wherein said effective amount of said at least one substance P antagonist is formulated into a topically applicable cosmetically- or dermatologically acceptable medium therefor.

--56. The method of Claim 55, wherein said substance P antagonist is a compound that (i) reduces the extravasation of plasma through the vascular wall caused by capsaicin or by antidromic nerve excitation, or (ii) inhibits the contraction of the smooth muscles induced by the administration of substance P, or (iii) a combination thereof, and wherein said effective amount of said at least one substance P antagonist is formulated into a topically applicable cosmetically-acceptable medium therefor.

--57. The method of Claim 55, wherein the method of treatment or prevention of sensitive, but not allergic, skin alleviates or prevents at least one neurogenic manifestation selected from the group consisting of skin irritation, desquamation, erythema, side effects of dysesthesia, side effects of overheating, and skin pruritus.

--58. The method of Claim 55, wherein the substance P antagonist is a nitrogen-containing heterocyclic compound.

--59. The method of Claim 55, wherein said substance P antagonist is a peptide.

--60. The method of Claim 55, wherein said substance P antagonist is a peptide selected from the group consisting of sendide and spantide II.

--61. The method of Claim 55, wherein said substance P antagonist is selected from the group consisting of 2-tricyclyl-2-aminoethane, spirolactame, quinuclidine, azacyclic, aminopyrrolidine, piperidine, aminoazeheterocyclic and isoindole compounds.

--62. The method of Claim 55, wherein the substance P antagonist is contained in an amount ranging from between 0.000001 to 5 percent by weight of the total weight of the composition.

--63. The method of Claim 62, wherein the substance P antagonist is contained in an amount ranging from between 0.0001 to 0.1 percent by weight of the total weight of the composition.

--64. The method of Claim 55, wherein said substance P antagonist is administered in a topically administrable form selected from the group consisting of aqueous and hydroalcoholic solutions, water-in-oil and oil-in-water emulsions, microemulsions, aqueous gels, anhydrous gels, serums and vesicular dispersions.

--65. The method of Claim 55, wherein said substance P antagonist is co-administered with at least one agent selected from the group consisting of anti-bacterials, anti-parasiticals, anti-fungals, anti-inflammatories, anti-pruriginous agents, anesthetics, anti-virals, keratolytic agents, anti-free radical agents, anti-seborrheal agents,

dandruff-fighting agents, acne-fighting agents, skin differentiating modulating agents, skin proliferation modulating agents, and skin pigmentation modulating agents.

--66. The method of Claim 55, wherein said substance P antagonist is co-administered with at least one agent selected from the group consisting of lidocaine, chlorohydrate, non-steroidal anti-parasiticals, and anti-inflammatory agents.

--67. The method of Claim 55, wherein said substance P antagonist is contained in a cosmetic or dermatological composition selected from the group consisting of cleansing creams, make-up removal creams, foundation creams, sunscreen creams, liquid foundations, make-up removal lotions, skin-care lotions, sunscreen lotions, skin-care gels, skin-care foams, tanning lotions, bath preparations, after-shave gels, after-shave lotions, depilatory creams, insect sting compositions, soaps, cleansing bars, aerosol compositions, hair care compositions, and mouth care compositions.

--68. The method of Claim 67, wherein said hair care composition is selected from the group consisting of a shampoo, setting lotion, hair treatment lotion, hair cream or gel, hair colorant, restructuring lotion, permanent wave composition, and an anti-hair loss lotion or gel.

--69. The method of Claim 67, wherein said mouth care composition is a toothpaste.

--70. The method of Claim 55, wherein said substance P antagonist is contained in an emulsion.

--71. The method of Claim 67, wherein said mouth care composition contains an ingredient selected from the group consisting of a surfactant, thickener, wetting agent, polishing agent, fluoride, and a sweetener.

--72. The method of Claim 70, wherein the emulsion contains a fatty phase, which comprises 5% to 80% by weight of the substance P antagonist-containing emulsion.

--73. The method of Claim 70, wherein the emulsion contains an oil, an emulsifier, and a co-emulsifier.

--74. The method of Claim 73, wherein the amount of emulsifier and co-emulsifier ranges from 0.3 to 30% by weight.

--75. The method of Claim 55, wherein said substance P antagonist is administered together with at least one additive selected from the group consisting of a water-absorbent or lipophilic gelling agent, water-absorbent or lipophilic active ingredient, preservative, antioxidant, solvent, perfume, filler, screen and coloring substance.

--76. The method of Claim 55, wherein said substance P antagonist is administered together with at least one oil selected from the group consisting of a mineral oil, vegetable oil, animal oil, synthetic oil, silicone-containing oil, and a fluorinated oil.

--77. The method of Claim 55, wherein said substance P antagonist is administered with at least one active ingredient selected from the group consisting of protein and protein hydrolyzates, amino acids, polyalcohols, urea, allantoin sugars and sugar derivatives, vitamins, hydroxy acids, retinol, tocopherol, ceramides, essential oils, and salicylic acid.

--78. The method of Claim 56, wherein said substance P antagonist is administered together with at least one agent selected from the group consisting of an agent that affects at least one of skin differentiation, proliferation and pigmentation, vitamin D, an estrogen, antibacterial agent, antiparasitic agent, antifungal agent, anti-inflammatory agent, anesthetic agent, anti-pruriginous agent, antiviral agent, keratolytic agent, anti-free radical agent, anti-seborrhea agent, anti-dandruff agent, and anti-acne agent.

--79. The method of Claim 55, wherein said substance P antagonist is administered together with at least one active ingredient that elicits an irritant side effect.

--80. The method of Claim 79, wherein said active ingredient is selected from the group consisting of an α-hydroxy acid, β-hydroxy acid, α-ketonic acid, β-ketonic acid,

retinoid, anthraline, anthranoid, peroxide, minoxidil, lithium salt, antimetabolite, and vitamin D compound.

--81. The method of Claim 55, wherein said substance P antagonist is contained in a cosmetically-acceptable medium.

--82. The method of Claim 55, which comprises topical application of said substance P antagonist to at least one of the skin, hair, or mucous membranes.

--83. The method of Claim 55, wherein said sensitive, but not allergic, skin is skin that is characterized by at least one symptom selected from the group consisting of tingling, burning, itching, and erythema after topical application of capsaicin.

--84. The method of Claim 83, wherein said at least one symptom is observed between 3 and 20 minutes after capsaicin application.

--85. A cosmetic or dermatological method for treating or preventing capsaicin-sensitive skin of an individual in need of such treatment, comprising topically applying to said capsaicin-sensitive skin an effective amount of at least one substance P antagonist-containing composition, and wherein said effective amount of said at least one substance P antagonist is formulated into a topically applicable cosmetically- or dermatologically-acceptable medium therefor.

--86. The method of Claim 85, wherein said substance P antagonist is a compound that (i) reduces the extravasation of plasma through the vascular wall caused by capsaicin or by antidromic nerve excitation, or (ii) inhibits the contraction of the smooth muscles induced by the administration of substance P, or (iii) a combination thereof, and wherein said effective amount of said at least one substance P antagonist is formulated into a topically applicable cosmetically-acceptable medium therefor.

--87. The method of Claim 85, wherein the method of treatment or prevention of capsaicin-sensitive skin alleviates or prevents at least one neurogenic manifestation selected from the group consisting of skin irritation, desquamation, erythema, side effects of dysesthesia, side effects of overheating, and skin pruritus.

--88. The method of Claim 85, wherein the substance P antagonist is a nitrogen-containing heterocyclic compound.

--89. The method of Claim 85, wherein said substance P antagonist is a peptide.

--90. The method of Claim 85, wherein said substance P antagonist is a peptide selected from the group consisting of sendide and spantide II.

--91. The method of Claim 85, wherein said substance P antagonist is selected from the group consisting of 2-tricyclyl-2-aminoethane, spirolactame, quinuclidine, azacyclic, aminopyrrolidine, piperidine, aminoazeheterocyclic and isoindole compounds.

--92. The method of Claim 85, wherein the substance P antagonist is contained in an amount ranging from between 0.000001 to 5 percent by weight of the total weight of the composition.

--93. The method of Claim 92, wherein the substance P antagonist is contained in an amount ranging from between 0.0001 to 0.1 percent by weight of the total weight of the composition.

--94. The method of Claim 85, wherein said substance P antagonist is administered in a topically administrable form selected from the group consisting of aqueous and hydroalcoholic solutions, water-in-oil and oil-in-water emulsions, microemulsions, aqueous gels, anhydrous gels, serums and vesicular dispersions.

--95. The method of Claim 85, wherein said substance P antagonist is co-administered with at least one agent selected from the group consisting of anti-bacterials, anti-parasiticals, anti-fungals, anti-inflammatories, anti-pruriginous agents, anesthetics, anti-virals, keratolytic agents, anti-free radical agents, anti-seborrheal agents,

dandruff-fighting agents, acne-fighting agents, skin differentiating modulating agents, skin proliferation modulating agents, and skin pigmentation modulating agents.

--96. The method of Claim 85, wherein said substance P antagonist is co-administered with at least one agent selected from the group consisting of lidocaine, chlorohydrate, non-steroidal anti-parasiticals, and anti-inflammatory agents.

--97. The method of Claim 85, wherein said substance P antagonist is contained in a cosmetic or dermatological composition selected from the group consisting of cleansing creams, make-up removal creams, foundation creams, sunscreen creams, liquid foundations, make-up removal lotions, skin-care lotions, sunscreen lotions, skin-care gels, skin-care foams, tanning lotions, bath preparations, after-shave gels, after-shave lotions, depilatory creams, insect sting compositions, soaps, cleansing bars, aerosol compositions, hair care compositions, and mouth care compositions.

--98. The method of Claim 97, wherein said hair care composition is selected from the group consisting of a shampoo, setting lotion, hair treatment lotion, hair cream or gel, hair colorant, restructuring lotion, permanent wave composition, and an anti-hair loss lotion or gel.

--99. The method of Claim 97, wherein said mouth care composition is a toothpaste.

--100. The method of Claim 85, wherein said substance P antagonist is contained in an emulsion.

--101. The method of Claim 97, wherein said mouth care composition contains an ingredient selected from the group consisting of a surfactant, thickener, wetting agent, polishing agent, fluoride, and a sweetener.

--102. The method of Claim 100, wherein the emulsion contains a fatty phase, which comprises 5% to 80% by weight of the substance P antagonist-containing emulsion.

--103. The method of Claim 100, wherein the emulsion contains an oil, an emulsifier, and a co-emulsifier.

--104. The method of Claim 103, wherein the amount of emulsifier and co-emulsifier ranges from 0.3 to 30% by weight.

--105. The method of Claim 85, wherein said substance P antagonist is administered together with at least one additive selected from the group consisting of a water-absorbent or lipophilic gelling agent, water-absorbent or lipophilic active ingredient, preservative, antioxidant, solvent, perfume, filler, screen and coloring substance.

--106. The method of Claim 85, wherein said substance P antagonist is administered together with at least one oil selected from the group consisting of a mineral oil, vegetable oil, animal oil, synthetic oil, silicone-containing oil, and a fluorinated oil.

--107. The method of Claim 85, wherein said substance P antagonist is administered with at least one active ingredient selected from the group consisting of protein and protein hydrolyzates, amino acids, polyalcohols, urea, allantoin sugars and sugar derivatives, vitamins, hydroxy acids, retinol, tocopherol, ceramides, essential oils, and salicylic acid.

--108. The method of Claim 86, wherein said substance P antagonist is administered together with at least one agent selected from the group consisting of an agent that affects at least one of skin differentiation, proliferation and pigmentation, vitamin D, an estrogen, antibacterial agent, antiparasitic agent, antifungal agent, anti-inflammatory agent, anesthetic agent, anti-pruriginous agent, antiviral agent, keratolytic agent, anti-free radical agent, anti-seborrhea agent, anti-dandruff agent, and anti-acne agent.

--109. The method of Claim 85, wherein said substance P antagonist is administered together with at least one active ingredient that elicits an irritant side effect.

--110. The method of Claim 109, wherein said active ingredient is selected from the group consisting of an α-hydroxy acid, β-hydroxy acid, α-ketonic acid, β-ketonic acid,

retinoid, anthraline, anthranoid, peroxide, minoxidil, lithium salt, antimetabolite, and vitamin D compound.

--111. The method of Claim 85, wherein said substance P antagonist is contained in a cosmetically-acceptable medium.

--112. The method of Claim 85, which comprises topical application of said substance P antagonist to at least one of the skin, hair, or mucous membranes.

--113. The method of Claim 85, wherein capsaicin-sensitive skin is skin that is characterized by at least one symptom selected from the group consisting of tingling, burning, itching, and erythema after topical application of capsaicin.

--114. The method of Claim 85, wherein said at least one symptom is observed between 3 and 20 minutes after capsaicin application.--

REMARKS

The foregoing claims are somewhat broader than the claims deemed allowable in parent Application No. 08/611,549, but are believed to be clearly patentable over the art for the reasons advanced during prosecution of the parent application.

If the Examiner deems these claims to be allowable except for possible obviousness-type double patenting rejections based on the parent application and commonly assigned

U.S. Patents No. 5,714,155 and 5,679,360, he is requested to telephone the undersigned so that appropriate terminal disclaimers can be promptly filed.

An early Action on the merits is believed to be in order and is earnestly solicited.

Respectfully submitted,

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